Worldwide Development
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Global Research & Development

June 3, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Dockets Management:

Re: **Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics**
[Docket No. 2005D-0112, 70 *Federal Register*, 17095, April 4, 2005]

Pfizer submits these attached comments to the draft Guidance for Industry on Clinical Trial Endpoints for the approval of Cancer Drugs and Biologics, Docket No. 2005D-0112, 70 *Federal Register*, 17095, April 4, 2005.

We find the guidance to be well written and agree with the general concepts outlined in this draft. We have only a few specific comments on the guidance as noted on the next page. Additionally, we would invite direct dialog if you would consider the opportunity valuable.

Sincerely,

Alison Russell /pip

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Associate Director
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Specific Comments:

Section	Comment
II.B	Line 126 • We would prefer to have a definitive statement as to the Agency's position. We suggest revising to "To satisfy this requirement, *it may be appropriate to* design single-arm studies..."
III	Table 1 • Regarding the advantages of Overall Response Rate (ORR), we suggest including 3 additional points: "Assessed earlier and in smaller studies compared with survival" and "Directly related to drug effect". • Regarding the advantages of Complete Response (CR), we suggest including 1 additional point: "Assessed earlier and in smaller studies compared with survival".
III.B.3	Line 284 • We assume that the Agency would also want to have this criteria • We would suggest revising the sentence to "protocol *and statistical analysis plan*..."
IV.D	Isolating drug effect in combination • Since chemosensitizers are not generally expected to have single agent activity. Therefore, it is not possible to isolate the effect of these agents. We suggest that this concept be acknowledged in this section.
Appendix 1	3rd bullet point • There is a need for more specific content in the guidelines for a mechanism to ensure the proper collection, assessment, and reporting of data at baseline and follow-up visits. We suggest revising to read "A mechanism ensures complete collection of data at critical times *at baseline* and during follow-up. It is important that the CRF ensures that all target lesions are assessed *at baseline* and each follow-up visit and that all required follow-up tests are done with the same imaging/measuring method *performed at baseline*."